

REMARKS

Claims 1, 3, 4, 6-36, 51, 52, 55, and 57-60 are pending, with claims 1, 4, 22, 34, 51, and 55 being independent. Claims 1, 4, 13, 22, and 55 have been amended; claims 5, 53, and 54 have been canceled; and claims 57-60 have been added. Support for the amendments and the new claims can be found in the originally-filed specification, at least at page 5, line 1 to page 6, line 15; page 9, line 7 to page 10, line 22; and Figs. 1-5, 7-11, 25, and 29. No new matter has been introduced.

Telephone Interview

The undersigned thanks Examiner Woo for discussing this application on January 9, 2008. During the interview, we discussed claims 1, 13, 22, and 55 and new dependent claims, which are presented in this reply as claims 57-60. We also discussed U.S. Patent Nos. 5,562,685 (Mollenauer); 3,645,222 (Zocher); and 5,437,680 (Yoon). Examiner Woo brought the following U.S. Patent Nos. to the attention of applicant: 592,926 (Caesar); 4,133,339 (Naslund); and 6,006,965 (Hamann). Applicant is citing these patents in an Information Disclosure Statement accompanying this reply.

An agreement was not reached but the Examiner and the undersigned discussed claim language that would possibly overcome the pending rejections. The undersigned proposed and the Examiner agreed to amendments to claims 1 and 55 to recite that the handle extends along an axial direction and that the opening is tapered from a distal closed edge of the opening to a proximal closed edge of the opening. The proposed and the Examiner agreed to an amendment to claim 22 to recite that the needle has a "through hole."

The amendments and the arguments presented in this reply capture the substance of the interview.

Claim Rejections

Claims 1, 3, 4, 6, 7, 9, 12, 13, 16-18, and 55 have been rejected as being unpatentable over Mollenauer in view of Zocher. Applicant requests withdrawal of this rejection for the following reasons.

Independent claim 1 recites a suturing device including a handle extending along an axial direction, an elongated shaft attached to a distal end of the handle, and a sharpened tip on a distal end of the elongated shaft. The sharpened tip including an exposed, tapered, and closed opening that is tapered from a distal closed edge of the opening to a proximal closed edge of the opening and is configured to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening.

Independent claim 55 recites a suturing device including a handle extending along an axial direction, an elongated shaft attached to a distal end of the handle, a sharpened tip on a distal end of the elongated shaft, and a suture coupled with the sharpened tip. The sharpened tip has a piercing portion configured to pierce tissue during a suturing procedure and has an exposed, tapered, and closed opening, where the opening is tapered from a distal closed edge of the opening to a proximal closed edge of the opening. The suture has a suture portion extending outward from the sharpened tip to permit the suture to be grasped and manipulated relative to the sharpened tip, the suture portion disposed to be carried by the sharpened tip through tissue which has been pierced by the piercing portion. The opening is configured to permit the suture to pass lengthwise through the opening.

Neither Mollenauer, Zocher, nor any proper combination of the two describes or suggests a sharpened tip at a distal end of an elongated shaft and having an exposed and closed opening that is tapered from a distal closed edge of the opening to a proximal closed edge of the opening, as recited in claims 1 and 55.

Mollenauer relates to a suturing instrument having a handle 12 or 102, a distal end 16 of the handle 12, and a coiled projection 14 or 104 extending from the handle distal end 16 or the handle 102. See Mollenauer at col. 4, lines 43-50; col. 9, lines 36-40; and Figs. 1 and 12. The coiled projection 14 has a pointed tip 36 with a bore opening 38 that extends through a center of the projection 14 but the projection 14 lacks an opening that is configured to trap suture.

The coiled projection 104 has a pointed tip 106 having an aperture 108 that extends transversely through the pointed tip 106. See Mollenauer at col. 9, lines 40-43 and Fig. 12. The aperture 108 is a closed eye that is "dimensioned sufficiently large to enable passing a length of suture through the aperture." See Mollenauer at col. 9, lines 42-44. Alternatively, the aperture 108 could be an open eye aperture 109. See Mollenauer at col. 9, lines 44-49 and Fig. 12. However, neither Mollenauer's aperture 108 nor aperture 109 is tapered and configured to trap a suture at a selected point within the aperture. Rather, the aperture 108 is designed with a straight edge and there is no point for suture to be trapped within the aperture 108. Moreover, there is no description that the aperture 109 would be tapered or would trap the suture at a selected point within the aperture 109.

Zocher does not remedy the failure of Mollenauer to describe or suggest this subject matter. In Zocher, a self-threading sewing machine needle includes a needle eye 15 that opens into a threaded slot 40. See Zocher at Figs. 1, 2, 6, and 7. Thus, Zocher lacks a closed opening and teaches away from a closed opening because Zocher's needle is designed to be self-threading. See Zocher at col. 1, lines 29-35. Additionally, Zocher's eye 15 does not taper from a distal closed edge to a proximal closed edge. Rather, Zocher's eye 15 tapers from a proximal closed edge that feeds into the slot 50 to a distal closed edge. See Zocher at Figs. 1, 6, and 7.

Moreover, one of ordinary skill in the art would not have been motivated to modify Mollenauer with the needle eye 15 of Zocher because any such modification would change the principle of operation of Mollenauer, in which the aperture 108 is placed at the end of the coiled projection 104 as a closed aperture. To modify Mollenauer with Zocher's needle eye 15 would also provide for a slot that would extend into the coiled projection 104, but such a modification of Mollenauer's instrument would render manufacture and operation of Mollenauer's instrument complicated and cumbersome.

Accordingly, for at least these reasons, claims 1 and 55 are allowable over Mollenauer. Claims 3, 6, 7, 9, 12, 13, and 16-18 depend from claim 1, and are allowable for at least the reasons that claim 1 is allowable and for containing allowable subject matter in their own right. For example, claim 13 recites that the elongated shaft extends along the axial direction and is centered on the axis on which the handle is centered on, and the sharpened tip is angularly bent about a tip axis that is non-parallel with the axial direction and is relative to said shaft in a

selected direction. Mollenauer does not describe or suggest such a sharpened tip. The pointed tip 106 in Mollenauer's instrument is bent along a spiral that extends from the handle 102 and the bending is about an axis that is parallel with the axis of the handle 102. See Mollenauer at Fig. 12.

As another example, claim 16 recites that the elongated shaft extends along an axial direction, and the sharpened tip is curved at least partially about the distal end of the shaft and about the axial direction. Mollenauer does not describe or suggest such a sharpened tip. In Mollenauer, the pointed tip 106 may be curved, but it is not curved partially about a distal end of the handle 102. Rather, the pointed tip 106 and the coiled projection 104 extend distally from the handle 102 and are not curved about the handle 102.

Independent claim 4 recites a suturing device including a handle extending along an axial direction, an elongated shaft attached to a distal end of the handle, and a sharpened tip on a distal end of the elongated shaft. The sharpened tip includes an exposed and closed opening that includes a central axial region that has said tapered configuration in which the central axial region is narrower than proximal and distal edge regions along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening. Applicant requests withdrawal of the rejection of claim 4 because neither Mollenauer, Zocher, nor any proper combination of the two describes or suggests such a central axial region with a tapered configuration. Mollenauer's aperture 108 lacks a tapered configuration. Moreover, while Zocher's eye 15 has a taper, it is not designed with a central axial region being narrower than proximal and distal edge regions; the taper is at an edge portion (the distal end) of Zocher's eye 15. See Zocher at Figs. 6 and 7.

Claims 21-24, 27-29, and 31 have been rejected as being unpatentable over Mollenauer in view of Zocher and Yoon. Applicant requests withdrawal of this rejection for the following reasons.

Claim 21 depends from claim 1, which was rejected as being unpatentable over Mollenauer in view of Zocher. As discussed above, neither Mollenauer, Zocher, nor any proper combination of the two describes or suggests a sharpened tip at a distal end of an elongated shaft and having an exposed and closed opening that is tapered from a distal closed edge of the

opening to a proximal closed edge of the opening, as recited in claim 1. Yoon does not remedy the failure of Mollenauer and Zocher to describe or suggest this subject matter.

Yoon relates to a needle 10 having a sharp tip 12, a curved body 14, and a proximal end 16. See Yoon at col. 4, lines 61-64 and Fig. 1. The needle 10 also includes a groove 22 formed in a convex side of the needle leading to a blind hole 24, where the groove 22 holds an end of suture material by friction or adhesive. See Yoon at col. 4, line 65 to col. 5, line 14 and Fig. 1. However, Yoon's sharp tip 12 lacks an exposed and closed opening that is tapered as recited in claim 1. Accordingly, claim 1 is allowable over any proper combination of Mollenauer, Zocher, and Yoon, and claim 21 is allowable for at least the reasons that claim 1 is allowable.

Independent claim 22 recites a suturing device including a handle extending along an axial direction, an elongated shaft attached to a distal end of the handle at a proximal end of the shaft, and a detachable needle at a distal end of the shaft. The needle has a side closed through hole into which a suture is attached. Applicant requests withdrawal of this rejection because neither Mollenauer, Zocher, Yoon, nor any proper combination of the three describes or suggests a detachable needle at a distal end of an elongated shaft and having a side closed through hole into which a suture is attached, as recited in independent claim 22, and because it would not have been obvious to modify Mollenauer to provide for a side closed through hole on a detachable needle.

Mollenauer describes an instrument that has a needle 78 that is detachable from a distal end 80 of a coiled projection 74 that extends from a handle 72. See Mollenauer at col. 7, line 62 to col. 8, line 31 and Fig. 10. Additionally, Mollenauer also described an instrument having a needle 90 that is detachable from a distal end 96 of a coiled projection 88 that extends from a handle 86. See Mollenauer at col. 8, lines 31-55 and Fig. 11. In both of these instruments, while the needle 78 and 90 is detachable, neither needle 78 nor needle 90 has a side closed through hole into which a suture is attached. Rather, as explained, suture 82 is connected to a rearward end of the needle 78 (presumably into a cavity of the needle 78) and filaments 92 are attached to a rearward end of the needle 90 (presumably into a cavity of the needle 90). See Mollenauer at col. 8, lines 10-16 and 39-44.

In Zocher, the eye 15 is not a closed hole and is not formed on a detachable needle, and in Yoon, the blind hole 24 that is formed in the needle sharp tip 12 is not a side closed through hole.

Additionally, it would not have been obvious to modify Mollenauer to provide a side closed through hole in the detachable needles 78 and 90 because Mollenauer's needles 78 and 90 receive, respectively, suture 82 and filaments 92 that extend from the inside of coiled projections 74, 88, respectively and therefore the opening in Mollenauer is aligned and positioned to receive the suture 82 and filaments 92. Any modification of Mollenauer's instrument would therefore change the principle of operation, which requires that the suture pass through the handle and the coiled projection before entering the needles 78 and 90. See MPEP § 2143.01VI.

Accordingly, claim 22 is allowable over any proper combination of Mollenauer, Zocher, and Yoon. Claims 23, 24, 27-29, and 31 depend from claim 22, and are allowable for at least the reason that claim 22 is allowable and for containing allowable subject matter in their own right. For example, claim 27 recites that the detachable needle is curved at least partially about a distal end of the shaft. None of the cited references describes or suggests a detachable needle that is curved at least partially about a distal end of the shaft.

New Claims

New claims 57-60 depend from claims 1 and 22, and are allowable for at least the reasons that claims 1 and 22 are allowable, and for containing allowable subject matter in their own right. For example, claims 57 and 59 recite that the sharpened tip includes at least one flat surface and the opening is positioned within the flat surface. None of the references describes or suggests such a flat surface.

Applicant : Jeffry B. Skiba
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Conclusion

In conclusion, applicant submits that all claims are in condition for allowance. The fee in the amount of \$120 in payment of the one-month extension of time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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/Diana DiBerardino/

Diana DiBerardino
Reg. No. 45,653

Fish & Richardson P.C.
1425 K Street, N.W.
11th Floor
Washington, DC 20005-3500
Telephone: (202) 783-5070
Facsimile: (202) 783-2331